

Improvement in Quality of Life Measures After Laparoscopic Antireflux Surgery

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Objective

To determine if patients with gastroesophageal reflux "well controlled medically" had a different quality of life from those with residual symptoms receiving aggressive medical therapy, and to determine whether laparoscopic antireflux surgery significantly altered quality of life in patients with gastroesophageal reflux.

Summary Background Data

Clinical determinants of outcome may not adequately reflect the full impact of therapy. The medical outcomes study short form (SF-36) is a well-validated questionnaire that assays eight specific health concepts in three general fields. It may provide a more sensitive tool for judging the success of antireflux therapy.

Methods

A total of 345 patients undergoing laparoscopic antireflux surgery completed at least one questionnaire during the study period. Preoperative questionnaires were completed by 290 patients, 223 completed a questionnaire 6 weeks after surgery, and 50 completed the same questionnaire 1 year after

surgery. A subgroup of 70 patients was divided before surgery into two groups on the basis of their response to standard medical therapy.

Results

Preoperative scores were extremely low. All eight SF-36 health categories improved significantly 6 weeks and 1 year after surgery. In the 70-patient subgroup, 53 patients (76%) underwent laparoscopic antireflux surgery because of symptoms refractory to medical therapy and 17 patients (24%) reported that their symptoms were well controlled but elected to have surgery because they wished to be medication-free. The preoperative quality of life scores of these two patient groups were equivalent in all but one category. Postoperative scores were significantly improved in all categories and indistinguishable between the two groups.

Conclusions

Laparoscopic antireflux surgery is an effective therapy for patients with gastroesophageal reflux and may be more effective than medical therapy at improving quality of life.

Modern medical and surgical therapies reliably produce disease improvement in patients with gastroesophageal reflux (GERD).¹⁻⁴ Assessment of symptoms has been traditionally coupled with objective data from esophagoscopy and/or ambulatory 24-hour pH monitoring to measure response to therapy. We have noticed that many patients (and physicians) equate symptom improvement with therapeutic success; however, patients may have to make significant lifestyle changes in concert with medical therapy to achieve adequate control of GERD. Lifestyle alterations include dietary modification, elevation of the head of the bed, abstinence from eating late in the day, and so forth. These

lifestyle modifications may greatly affect the ability of patients with GERD to eat, sleep, and socialize, consequently affecting their quality of life (QOL). QOL assessment for GERD may represent an outcome that is more sensitive than clinical outcome scores alone by including questions sensitive to the behavioral modifications that adversely affect QOL in patients with GERD.

The aims of this study were to determine if the compromises that patients with GERD made to control their symptoms could be detected with an established QOL tool, to determine if groups "well controlled medically" had QOL differences from those with residual symptoms receiving aggressive medical therapy, and to determine whether laparoscopic antireflux surgery significantly altered QOL in patients with GERD.

We chose to use the generic (*i.e.*, not disease-specific)

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Medical Outcome Study 36-item short form (MOS SF-36) as our instrument of outcome analysis. The SF-36 is a well-validated, reliable, and sensitive questionnaire that measures eight important health concepts.⁵⁻¹² Use of a well-validated questionnaire allows confidence in the significance of the scores and allows comparison with other disease states studied with the SF-36.

PATIENTS AND METHODS

All patients referred to the Emory Swallowing Center for the consideration of surgery for GERD were considered for this study. All patients underwent a full medical history and physical examination. During the initial evaluation, foregut symptoms were scored by the patient, and a computerized SF-36 form was completed by the patient after explanation by a research nurse. Esophagogastroduodenoscopy was performed in all patients with persistent or recurrent symptoms after a 6-week course of standard medical therapy. Esophageal manometry and barium swallow were also performed routinely. Twenty-four-hour ambulatory esophageal pH monitoring was administered selectively in patients with atypical symptoms or nonerosive esophagitis.¹³

Patients were considered for surgery if the above investigations confirmed the diagnosis of GERD and either of the following occurred: symptoms persisted (with or without improvement) despite aggressive medical therapy, or symptoms were eliminated with medical therapy but surgery was chosen because the patient wished (for a number of reasons) to discontinue medical therapy.

Surgical techniques employed were previously described.¹⁴ A loose 2-cm Nissen fundoplication was performed over a 60F bougie dilator (or smaller in patients with stricture) in patients with normal preoperative esophageal body function. A 2-cm 270° posterior fundoplication (Toupet) over a similar-sized bougie dilator was performed in patients with poor preoperative esophageal body function (*i.e.*, peristaltic contraction in <70% of wet swallows and/or esophageal contraction pressures <30 mmHg). The greater curvature of the stomach was mobilized in all patients by dividing the short gastric vessels and posterior fundic attachments. The crura were closed snugly behind the esophagus in all patients.

Patients were discharged from the hospital 1 to 3 days after surgery and were urged to return to full activities and work within 3 weeks of surgery. Postoperative visits occurred at 4 to 6 weeks and yearly after surgery for the first 2 years. SF-36 forms were administered at each visit.

The SF-36 measures eight important health concepts:

1. Physical functioning, which measures physical activity limitations resulting from health problems
2. Role functional-physical, which measures the limitations of usual role activities resulting from problems in physical health
3. Bodily pain, which measures perception of bodily pain

4. General health, which measures general health perception
5. Vitality, which measures energy level and fatigue
6. Social functioning, which measures social activity limitations resulting from emotional or physical problems
7. Role functional-emotional, which measures the limitations of usual role activities resulting from emotional problems
8. Mental health, which measures psychological distress and well-being.

Completed SF-36 forms were processed by Response Healthcare Information Management, Inc., East Greenwich, RI. Statistical analysis was performed using StatView II, version 1.04 software. The results of preoperative and postoperative questionnaires were compared. A rank sum test was used to compare unmatched data, and a signed rank test was used to compare scores from the same patient before and after surgery. Although the eight health concepts generated from the SF-36 forms are reported on scales from 0 to 100, they may not follow a normal distribution.¹⁵ The results were also compared with established scores of general health from a representative sample of healthy persons in the United States and established scores from patients with congestive heart failure.¹⁶

Patients

Seventy patients were part of an initial pilot study. The mean age of the patients was 48 ± 13 years. There were 40 (57%) men and 30 (43%) women. Patients were asked if their symptoms were completely or only partially controlled with medication. Seventeen (24%) of these patients reported that their reflux symptoms were completely controlled with medical therapy, and 53 (76%) had one or more refractory symptoms. Twelve (71%) of the 17 patients who reported that their symptoms were controlled with medical therapy were taking omeprazole (proton pump inhibitor [PPI]): 11 were taking ≥ 20 mg daily and 1 was taking 40 mg daily. The other five patients' symptoms were controlled with high-dose histamine antagonists (H_2 blockers). Four patients taking PPIs and two patients taking H_2 blockers were also taking promotility agents. Medication data were available on 50 of the 53 patients whose symptoms were refractory to medical therapy. Forty-two patients were taking PPIs regularly: 32 were taking ≥ 20 mg daily, 9 were taking 40 mg daily, and 1 was taking 60 mg daily. Eight patients preferred high-dose H_2 blockers over PPI therapy. Twelve patients taking PPIs and two patients taking H_2 blockers were also taking promotility agents.

In our cohort of 345 patients, 289 completed a preoperative questionnaire, 223 completed a postoperative questionnaire, 181 completed both pre- and postoperative questionnaires, and 50 completed the questionnaire 1 year after surgery. Questionnaires were given to all patients visiting

Table 1. PRE- AND POSTOPERATIVE SF-36 SCORES OF THE 323-PATIENT COHORT WITH ESTABLISHED VALUES FOR PATIENTS WITH CONGESTIVE HEART FAILURE AND HEALTHY CONTROLS

SF-36 Category	Preop (n = 290)	6 weeks postop (n = 223)	1 year postop (n = 50)	Congestive Heart Failure (n = 216)	US Norms (n = 2474)
Physical functioning	65.5 (28.1)	80.7 (22.2)	80.5 (26.4)	48 (31)	84.2 (23.3)
Role physical	47.6 (43.5)	64.9 (42.0)	71.5 (41.1)	34 (40)†	81.0 (34.0)
Bodily pain	51.5 (27.4)	66.7 (23.0)	70.0 (28.5)	63 (31)†	75.2 (23.7)
General health	54.9 (24.7)	72.3 (20.4)	69.7 (21.8)	47 (24)†	72.0 (20.3)
Vitality	38.4 (24.9)	57.5 (22.3)	63.7 (23.3)	44 (24)*	60.9 (21.0)
Social functioning	62.5 (29.4)	81.9 (22.3)	83.6 (24.5)	71 (33)*	83.3 (22.7)
Role emotional	59.1 (43.2)	84.9 (31.93)	86.7 (30.6)	64 (43)‡	81.3 (33.0)
Mental health	63.6 (21.7)	78.8 (16.6)	75.4 (17.5)	75 (21)†	74.7 (18.1)

All data reported as mean (standard deviation)

p < 0.0005, preop vs. postop (6 weeks & 1 year) in all categories.

p = NS, 6 weeks postop vs. 1 year postop in all categories.

* p < 0.05 preop GERD vs. CHF, ANOVA.

† p < 0.001 preop GERD vs. CHF, ANOVA.

‡ p = NS preop GERD vs. CHF, ANOVA.

the Emory Swallowing Center for surgical evaluation or postoperative visit between February 23, 1994, and January 9, 1997. The mean age of the patients was 49 ± 14 years. There were 182 (53%) men and 163 (47%) women. Most of the patients (89%) underwent surgery for the treatment of typical reflux symptoms of heartburn, regurgitation, and/or dysphagia. More than half (64%) also had one or more atypical symptoms of asthma, hoarseness, chest pain, and/or dysphagia. Only 11% had atypical symptoms without significant heartburn.³

RESULTS

All eight SF-36 scores showed significant improvement 6 weeks after surgery compared with the preoperative scores (p < 0.0005). This difference remained significant 1 year after surgery. The results of the entire cohort group are summarized in Table 1 and Figure 1.

The preoperative scores were comparable to, and in some categories slightly lower than, those established from a population of patients with congestive heart failure.¹⁶ The postoperative scores improved to those established for a healthy population representing U.S. norms.¹⁶ These data are summarized in Table 1 and Figure 2.

One hundred eighty-one patients in our cohort completed both preoperative and postoperative questionnaires and acted as their own controls. Scores obtained for this group of patients were similar to those of the larger unpaired group. Twenty-five patients in this group also completed SF-36 questionnaires 1 year after surgery. Once again, their scores were significantly higher than those obtained before surgery, despite the relatively small sample size. These data are summarized in Table 2 and Figure 3.

Seventy patients were part of an initial pilot study. Fifty-

three patients (76%) underwent laparoscopic antireflux surgery because of symptoms refractory to medical therapy. Twenty-four (45%) had persistent regurgitation while receiving medical therapy. Ten (19%) continued to have chronic cough, 12 (23%) had persistent chest pain, 5 (9%) had persistent hoarseness, and 2 (4%) had troublesome asthma despite medical therapy. Fourteen (26%) had some heartburn or dysphagia while receiving medical therapy. Seventeen (24%) reported that their symptoms were well controlled with medical therapy but elected to have surgery because of concerns about medication safety, cost, or dependence. Pre- and postoperative scores of these 70 patients were similar to those of the large cohort. Other than role-physical scores, there were no significant differences between the preoperative scores of patients who reported that their symptoms were well controlled with omeprazole and

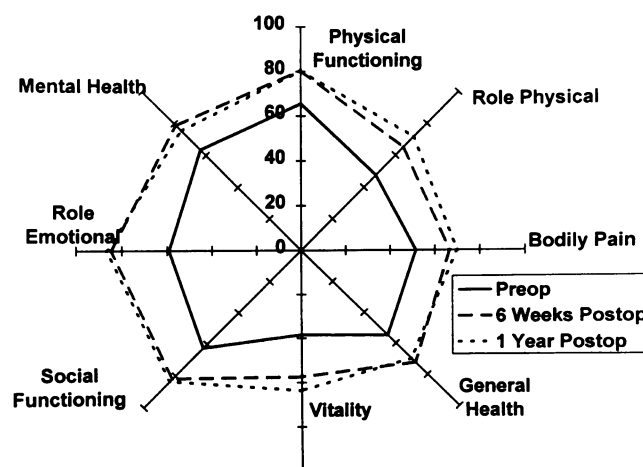


Figure 1. Polar graph of preoperative and postoperative SF-36 scores of the 345-patient cohort.

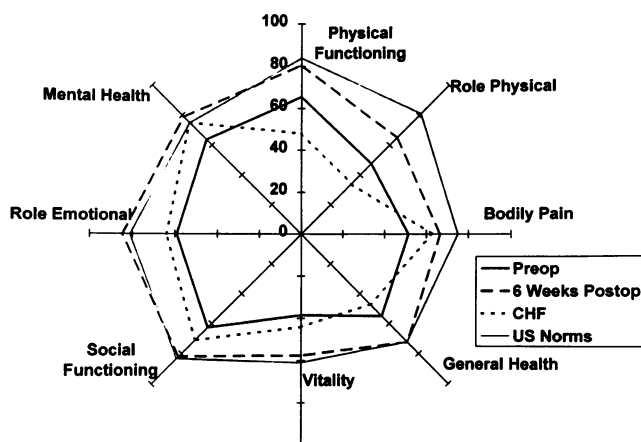


Figure 2. Polar graph of preoperative and postoperative SF-36 scores, with established values for patients with congestive heart failure (CHF) and healthy controls (US Norms).

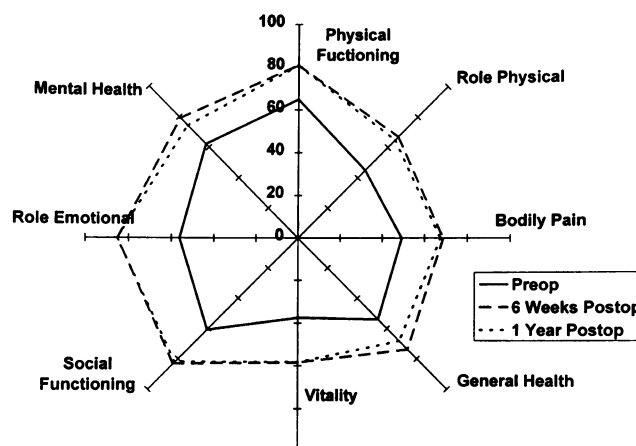


Figure 3. Polar graph of preoperative and postoperative SF-36 scores of the 181 patients completing both pre- and postoperative questionnaires.

those with symptoms refractory to medical therapy. Postoperative scores were similar between patients with preoperative symptoms refractory to therapy and patients with preoperative symptoms controlled with medication (Table 3, Fig. 4). Both groups had significant improvement in their postoperative scores as compared to their preoperative values.

DISCUSSION

Guidelines for the management of GERD promulgated by the American College of Gastroenterology have as their goal the elimination of reflux symptoms.¹⁷ There are numerous studies demonstrating the ability of medical therapy and antireflux surgery to eliminate reflux symptoms, but only a handful of studies have addressed the ability of antireflux therapy to alter QOL. Most of these reports have

used disease-specific, often nonvalidated questionnaires to test patients' response to surgery.¹⁸⁻²²

The issues surrounding QOL measurement after antireflux surgery are clearly outlined in a 1992 study.¹⁸ Objective measurements, although extremely important, have little to do with the measurement of patient satisfaction after antireflux surgery.¹⁸ Glise et al^{19,20} used two independent QOL tools to measure the effects of antireflux surgery on the QOL of 40 patients with GERD. Both disease-specific and non-disease-specific questionnaires were administered before and after surgery. Postoperative improvements were

Table 2. PRE- AND POSTOPERATIVE SF-36 SCORES OF PATIENTS COMPLETING PRE- AND POSTOPERATIVE QUESTIONNAIRES

SF-36 Category	Preop (n = 181)	6 weeks postop (n = 181)	1 year postop (n = 25)
Physical functioning	64.9 (27.2)	81.2 (21.7)	81.0 (25.7)
Role physical	45.0 (43.5)	66.9 (41.4)	64.7 (44.4)
Bodily pain	49.3 (26.9)	66.6 (21.8)	67.7 (27.0)
General health	54.0 (24.9)	73.7 (19.9)	68.1 (23.3)
Vitality	37.4 (24.5)	58.4 (22.1)	58.3 (22.6)
Social functioning	60.8 (28.9)	83.2 (21.5)	82.0 (25.6)
Role emotional	56.1 (43.5)	85.2 (30.6)	85.4 (31.6)
Mental health	62.1 (21.3)	79.0 (16.5)	74.1 (19.5)

All data reported as means \pm (standard deviation)

p < 0.0005, preop vs. 6 weeks postop, p < 0.05, pre vs. 1 yr. postop, p = NS, 6 weeks postop vs. 1 year postop.

Table 3. PRE- AND POSTOPERATIVE SF-36 SCORES OF PATIENTS WITH MEDICALLY CONTROLLED SYMPTOMS AND PATIENTS WITH SYMPTOMS REFRACTORY TO MEDICAL THERAPY

SF-36 Category	Preoperative		Postoperative	
	Controlled (n = 17)	Refractory (n = 53)	Controlled (n = 17)	Refractory (n = 53)
Physical functioning	70.7 (28.0)	62.3 (28.8)	85.9 (20.0)	85.5 (20.2)
Role physical	66.2 (44.1)*	38.4 (45.5)*	80.9 (28.7)	83.0 (32.4)
Bodily pain	57.8 (29.8)	45.3 (27.8)	76.8 (23.1)	73.4 (18.6)
General health	55.9 (26.3)	48.0 (26.7)	83.6 (11.7)	78.2 (17.6)
Vitality	35.2 (25.2)	46.5 (26.3)	68.8 (18.3)	65.8 (18.5)
Social functioning	72.1 (26.3)	55.4 (30.6)	92.6 (13.3)	89.1 (16.1)
Role emotional	60.8 (48.9)	46.5 (45.0)	96.1 (11.1)	90.3 (25.2)
Mental health	67.5 (24.4)	62.5 (21.3)	85.9 (13.1)	84.1 (12.0)

All data reported as means \pm (standard deviation)

p = NS, preoperatively controlled vs. refractory, preop except role physical *(p < 0.05).

p = NS, postoperatively controlled vs. refractory.

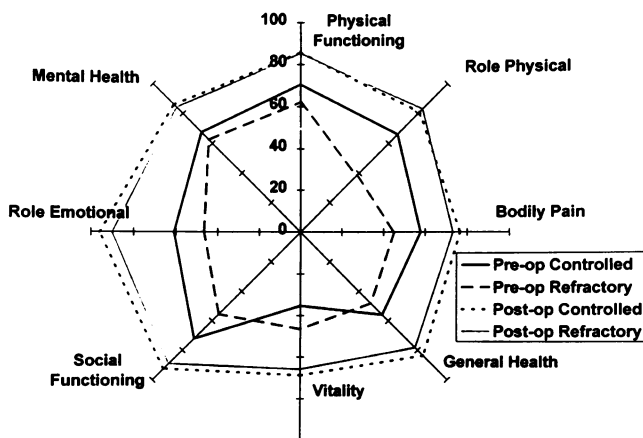


Figure 4. Polar graph of preoperative and postoperative SF-36 scores of patients with symptoms well controlled with omeprazole and patients with symptoms refractory to omeprazole therapy.

noted using both tools, with scores as good as or better than those seen on optimal medical therapy. A more recent study reported on a new, nonvalidated, disease-specific QOL tool (GERD-HRQL) administered to 72 patients with GERD who were undergoing medical therapy (47) or surgery (25).²¹ The questionnaire's focus was primarily on heartburn and dysphagia symptoms; it did not address atypical manifestations of GERD. Follow-up was limited to 6 months. One interesting observation was that initial scores for patients who eventually chose surgery were significantly lower than initial scores for patients who were ultimately satisfied with medical management. These scores were found to correlate poorly with SF-36 scores in a subsequent study, suggesting perhaps a limited focus of the GERD-HRQL.²² Although these studies provide useful information, they do not provide the platform to compare QOL in patients with GERD with other chronic disabling conditions.²³⁻³⁴

Although one might expect that the preoperative scores (SF-36) of patients with severe GERD would be below the norm, it was surprising to find how poor the scores actually were. These low scores are comparable to those reported by others in inadequately treated GERD patients.^{19,20,35} In many cases, the scores were comparable to established values for severe chronic disease states often associated with permanent disability, such as patients with congestive heart failure. As might be expected, scores for physical activity in patients with congestive heart failure were lower than in GERD patients, but other parameters, such as bodily pain, vitality, social functioning, and emotional and mental health, were more impaired in patients with GERD than in patients with congestive heart failure. A control group of normals and patients with chronic disease from the same locality would provide a more rigorous comparison. Those data were not available at the time of this study; therefore, comparisons with national averages were used.

In our pilot study of 70 patients, 26% reported that their symptoms were well controlled on medical therapy, but

only one SF-36 score (role functioning-physical) was significantly better than in patients whose symptoms were refractory to medical therapy. This implies that patients whose symptoms were well controlled with medication were able to perform work and other daily activities with little interference from reflux symptoms. Despite the lack of statistical significance, the polar graph (see Fig. 4) appears generally to show that QOL for patients with symptoms controlled by medication is better than for patients whose symptoms are refractory to medical therapy. Nonetheless, it appears that symptom control with antireflux surgery improves QOL scores to a greater extent than symptom control with medical therapy in patients with severe GERD. This finding must be interpreted with caution, however. The 17 patients claiming to be symptom-free while receiving medications chose to seek surgical consultation. The decision to elect antireflux surgery may indicate a difference between these patients and patients symptom-free while receiving medical therapy who are not interested in antireflux surgery. Also, because of the small number of patients in the medically well-controlled group, a type II statistical error is possible.

Nonetheless, others have recently shown SF-36 physical and mental health scores of patients with GERD receiving PPI therapy to be significantly lower than those of the general population.³⁵ We are currently gathering comparative SF-36 data on patients with medication-dependent GERD whose symptoms are well controlled on medical therapy and have no interest in surgery. A group of medically controlled patients with equally matched symptom scores, ambulatory pH results, and SF-36 scores would be an ideal control group for our patients who underwent laparoscopic antireflux surgery.

Our patient population represents a population with severe GERD. In our patients, the mean duration of disease is 8 years. Many have been through a variety of therapies and continue to have symptoms refractory to medical therapy, most commonly persistent regurgitation. Despite eradication of heartburn with medication, many of our patients still have troublesome regurgitation that forces them to make significant lifestyle modifications. Many sleep with the head of the bed elevated or even in recliners, and avoid evening meals in an attempt to minimize regurgitation. These measures may eliminate disease-specific symptoms but may have a negative impact on a patient's perception of QOL.

After laparoscopic antireflux surgery, SF-36 scores return to the normal range. The improvement in QOL scores is not a "honeymoon" effect, as illustrated by the persistence of good scores 1 year after surgery. Statistical significance was easily achieved with a small cohort size at 1 year after surgery. Further follow-up of this cohort at 5-year intervals will best allow us to quantify the durability of this intervention. These data suggest that patients are able to obtain relief from reflux symptoms after laparoscopic antireflux surgery without acquiring postoperative side effects that have a significant impact on their perceived QOL. The poor corre-

lation of SF-36 scores with specific symptom scores suggests that QOL tools represent an independent measure of clinical outcome, and reinforces the importance of multiple outcome measurement in the study of patient satisfaction and response to therapy.³⁶ Laparoscopic antireflux surgery is an effective therapy for patients with GERD. In addition, surgery may be more effective than medical therapy at improving QOL for patients with GERD, including those who report that their symptoms are well controlled with medication.

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